**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF MICHIGAN**
**SOUTHERN DIVISION**

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| KARROLD L. DUDLEY,<br><br>Plaintiff,<br>v.<br><br>AZIYO BIOLOGICS, INC.,<br>MEDTRONIC USA, INC., and<br>MEDTRONIC, INC.,<br>jointly and severally,<br><br>Defendants. | No. 2:21-cv-11813-XXX-XXX<br><br>Hon.<br><br>Mag. Judge |
| DARRYL K. SEGARS (P54997)<br>**THE SEGARS LAW FIRM**<br>Attorneys for Plaintiff<br>615 Griswold St., Suite 913<br>Detroit, MI 48226<br>Phone/Fax: (313) 859-5500/5506<br>email: segarslaw@hotmail.com | |

## COMPLAINT AND JURY DEMAND

**NOW COMES** Plaintiff, Karrold L. Dudley, by and through her attorneys, and for her complaint against Defendants, Aziyo Biologics, Inc., Medtronic USA, Inc., and Medtronic, Inc. (collectively, "Defendants"), alleges as follows:

## INTRODUCTION

l. This action seeks to recover damages for the personal injuries suffered by KARROLD L. DUDLEY, which were the direct and proximate result of the wrongful conduct of AZIYO BIOLOGICS, INC., MEDTRONIC USA, INC., and MEDTRONIC, INC. in connection with the research, testing, design, development, manufacture, production, inspection,

labeling, advertisement, marketing, promotion, sale, and distribution of FiberCel Fiber Viable Bone Matrix ("FiberCel").

**PARTIES, JURISDICTION AND VENUE**

2. KARROLD L. DUDLEY ("Plaintiff') is and at all relevant times was a resident of the City of Detroit, County of Wayne, State of Michigan.

3. Defendant AZIYO BIOLOGICS, INC. ("Aziyo") is a Delaware corporation, whose registered agent for service of process in Michigan is Lawyers Incorporating Service, 2900 West Rd., East Lansing, MI 48823. Aziyo's principal place of business is located at 12510 Prosperity Drive, Suite 370, Silver Springs, MD 20904. Upon information and belief, Aziyo does business throughout the United States, including conducting regular business in Michigan.

4. Aziyo sells a variety of medical products, including implantable electronic devices, orthopedic and spinal repair products, and soft tissue reconstruction products.

5. Upon information and belief, Aziyo developed, manufactured, marketed, promoted, distributed, supplied and/or sold FiberCel which was implanted into Plaintiff and which is the subject of this complaint.

6. Defendant MEDTRONIC USA, INC. is incorporated in Minnesota, having its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432-5604. Its registered agent for service of process in Michigan is Lawyers Incorporating Service, 2900 West Rd., East Lansing, MI 48823. MEDTRONIC USA, INC. does business throughout the United States, including conducting regular business in Michigan.

7. Defendant MEDTRONIC, INC. is incorporated in Minnesota, having its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432-5604. Its registered agent for service of process in Michigan is Lawyers Incorporating Service, 2900 West Rd., East

Lansing, MI 48823. MEDTRONIC, INC. does business throughout the United States, including conducting regular business in Michigan.

8. MEDTRONIC USA, INC, and MEDTRONIC, INC. (collectively, "Medtronic") develop therapeutic and diagnostic medical products, and are among the world's largest medical technology, services, and solutions companies.

9. Upon information and belief, Medtronic was designated as the exclusive U.S. distributor of the FiberCel manufactured by Defendant Aziyo.

10. At all times relevant, Medtronic distributed, supplied and/or sold FiberCel in Michigan which was implanted into Plaintiff and which is the subject of this complaint.

11. Defendants, at all times relevant to this lawsuit, manufactured, developed, designed, marketed, distributed, promoted, supplied and/or otherwise sold (directly or indirectly) FiberCel to various locations for use in surgeries requiring bone grafting, including to Ascension Providence Hospital in Michigan where it was surgically implanted into Plaintiff KARROLD L. DUDLEY, causing her to suffer harm as described more fully herein.

12. This claim arises out of a lumbar spine surgery performed on Plaintiff, KARROLD L. DUDLEY, at Ascension Providence Hospital in Southfield, Michigan on March 12, 2021, in which FiberCel was surgically implanted into her body.

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332(a)(1) because this case is a civil action where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between citizens of different States.

14. Venue is properly set in this District pursuant to 28 U.S.C. §1391(b) since Defendants transact business within this judicial district. Likewise, a substantial part of the events giving rise to the claim occurred within this judicial district.

15. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in the State

of Michigan, such that requiring an appearance does not offend traditional notions of fair play and substantial justice. Further, Defendants have maintained registered agents in the State of Michigan.

16. This court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process in that Defendants, acting through their agents or apparent agents, committed one or more of the following: a. The transaction of any business within the state; b. The making of any contract within the state; c. The commission of a tortious act within this state; and d. The ownership, use, or possession of any real estate situated within this state.

17. Requiring Defendants to litigate these claims in Michigan does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. All of Plaintiff's claims arise in part from conduct Defendants purposefully directed to Michigan.

## FACTUAL ALLEGATIONS

18. FiberCel Fiber Viable Bone Matrix ("FiberCel") is made from human tissue consisting of cancellous bone particles with preserved cells, combined with demineralized cortical fiber. It is engineered to be like natural tissue and is used as a bone void filler in various orthopedic and spinal procedures. The allografts contain the scaffold, growth factors and cells required for regeneration critical for successful bone formation.

19. FiberCel is marketed for use in orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft. FiberCel is made with donor tissue and growth factor cells.

20. On June 20, 2019, Aziyo announced it had signed an exclusive, multiyear distribution agreement with defendant Medtronic in the U.S. orthopedic market. According to

the agreement, Aziyo agreed to manufacture and supply FiberCel to Medtronic for distribution through the company's sales and marketing organization.

21. On June 2, 2021, the United States Food & Drug Administration (FDA) issued an urgent voluntary recall of FiberCel; specifically three products from Donor Lot Number NMDS210011: VMB9901, VBM9905, and VBM9910.

22. Aziyo initiated the voluntary recall in response to reports of patients testing positive for Tuberculosis and post-surgical infections following the surgical implantation of FiberCel as part of an orthopedic or spinal procedure.

23. Tuberculosis ("TB") is an infectious disease caused by bacteria known as Mycobacterium tuberculosis. TB is highly contagious, and mostly impacts the lungs, but can also spread through the lymph nodes to other parts of the body, including the kidneys, brain, and spine.

24. Once mycobacterium tuberculosis is introduced to the body, the bacteria must then proliferate within the new host for the host to develop disease. When this bacteria is introduced in a surgical wound, the patient is already in an immunocompromised position, causing them to have an increased likelihood of developing TB, which can be fatal.

25. The recalled contaminated FiberCel lot contained approximately154 units delivered to approximately 20 states, including Michigan.

26. Upon information and belief, Ascension Providence Hospital received several units from the contaminated FiberCel Donor Lot No. NMDS210011, and the contaminated units were implanted into several patients, including Plaintiff.

27. Defendant Aziyo has acknowledged that the Centers for Disease Control and Prevention (CDC) has reported post-surgical infections consistent with TB in seventy-two (72) of the one hundred thirteen (113) patients that received FiberCel from Donor Lot No.

NMDS210011. At least eight (8) patients that have received FiberCel from this Donor Lot have died and scores of others have tested positive for TB, including Plaintiff.

28. This recall acknowledged that viruses and bacteria, including Tuberculosis, can be transplanted into patients along with the FiberCel product.

29. Plaintiff KARROLD L. DUDLEY underwent lumbar spine surgery on March 12, 2021 at Ascension Providence Hospital in Southfield, Michigan.

30. Plaintiff KARROLD L. DUDLEY' surgery included utilization of FiberCel from Donor Lot Number NMDS210011.

31. Unbeknownst to Plaintiff or her physicians at the time of her surgery, the FiberCel implanted into Plaintiff was contaminated with tuberculosis.

32. Following her March12, 2021 operation, Plaintiff KARROLD L. DUDLEY tested positive for tuberculosis.

33. Plaintiff's tuberculosis was caused by the contaminated and recalled FiberCel used in her lumbar spine surgery.

34. Plaintiff was forced to undergo two (2) painful and complicated revision surgeries to address the infection caused by the contaminated FiberCel product.

35. Plaintiff underwent revision surgeries to treat the infected area around the contaminated site on March 26, 2021 and June 8, 2021 at Ascension Providence Hospital in Southfield, Michigan.

36. Due to the need for a revision surgeries, Plaintiff's has suffered decreased range of motion and more substantial permanent injury when compared to the long term outlook of her original fusion surgery.

37. Plaintiff's revision surgeries have subjected her to much greater risks of complication than she had before the revision surgery.

38. Plaintiff's diagnosis of tuberculosis will require extensive and invasive medical protocols to manage the manifestation of this disease.

39. Plaintiff will require continued medical monitoring and treatment now and into the future in order to monitor Plaintiff's health related to the ongoing and serious nature of her tuberculosis diagnosis.

40. Plaintiff would not have suffered from tuberculosis, as well as the need to undergo subsequent revision surgeries, had Defendants sold and distributed a product that was free from tuberculosis contamination.

41. As a direct and proximate result of Plaintiff's exposure to Defendants' contaminated FiberCel product used in her lumbar spine surgery, Plaintiff has suffered and continues to suffer from severe pain and discomfort, emotional distress, the loss of daily functions, and economic loss, including, but not limited to, present and future medical expenses, lost earnings and future lost earning capacity, all of which are a direct result of Defendants' liability producing conduct.

**COUNT I**
**NEGLIGENCE**

42. Plaintiff incorporates the foregoing paragraphs as though the same were set forth at length herein, word for word.

43. Defendants owed a duty to KARROLD L. DUDLEY to exercise reasonable care designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and distribution of FiberCel into the stream of commerce, including a duty to assure that the FiberCel would not cause those who used it, including KARROLD L. DUDLEY, to suffer adverse harmful effects.

44. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of FiberCel.

45. Defendants knew or should have known that those individuals who used the defective FiberCel were at risk for suffering harmful effects from it, including, but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

46. Defendants were negligent in designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of FiberCel. The negligence of Defendants, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

a. Designing, manufacturing, producing, creating, and/or promoting FiberCel without adequately, sufficiently, or thoroughly testing the FiberCel units to ensure they were free from contamination of communicable diseases, including but not limited to, tuberculosis;

b. Not conducting a sufficient quality control testing program to determine whether or not the subject FiberCel was manufactured properly and was free from contamination or other defects making it unsafe for users of the product;

c. Failing to adequately and properly obtain and review complete donor medical history;

d. Negligently failing to timely recall their dangerous and defective FiberCel lots at the earliest date that it became known that certain lots of FiberCel were, in fact, dangerous and defective;

e. Negligently manufacturing FiberCel in a manner that was dangerous to those individuals who had FiberCel transplanted into their bodies;

f. Negligently producing FiberCel in a manner that was dangerous to those individuals who had it transplanted into their bodies;

g. Failing to warn individuals who were using the product of the risks of contracting tuberculosis; and

h. Were otherwise careless and negligent.

47. Defendants knew or should have known that consumers, such as Plaintiff KARROLD L. DUDLEY, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

48. Defendants' negligence was the proximate cause of KARROLD L. DUDLEY's physical, mental, emotional injuries and harm, and economic loss.

49. By reason of the foregoing, Defendants are liable to KARROLD L. DUDLEY for all of her injuries, harm, damages, as well as her economic and non-economic losses in an amount to be determined in the future.

**COUNT II**
**BREACH OF IMPLIED WARRANTY**

50. Plaintiff incorporates the foregoing paragraphs as though the same were set forth at length herein, word for word.

51. Defendants are in the business of designing, manufacturing, supplying, selling, and placing into the stream of commerce certain goods, including FiberCel.

52. By placing FiberCel into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

53. The FiberCel placed into the stream of commerce by Defendants and implanted into Plaintiff was contaminated, leading those persons, including Plaintiff, who received FiberCel implants to develop tuberculosis, and accordingly, was not fit, safe, or merchantable for its intended use.

54. The contamination in the FiberCel manufactured, supplied, and placed into the stream of commerce by Defendants was present at the time the FiberCel units left Defendants' control and at the time it was implanted into Plaintiff as part of her spinal operation.

55. Defendants breached the implied warranty for FiberCel because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiff KARROLD L. DUDLEY, including her development of tuberculosis.

56. Plaintiff KARROLD L. DUDLEY was a foreseeable user of the FiberCel designed, manufactured, and placed into the stream of commerce by Defendants.

57. By reason of the foregoing, Defendants are liable to Plaintiff KARROLD L. DUDLEY for her injuries, harm, damages, as well as her economic and non-economic losses in an amount to be determined at trial.

**COUNT III**
**BREACH OF EXPRESS WARRANTY**

58. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if they were set forth at length herein, word for word.

59. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants and their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the public, that FiberCel is safe, effective, fit, and proper for its intended use. Plaintiff and Plaintiff's physicians utilized FiberCel relying upon these warranties.

60. Defendants' own promotional material states that FiberCel is processed in sterile conditions, and is screened for bacteria and communicable disease.

61. In utilizing FiberCel, Plaintiff relied on the skill, judgment, representation, and the foregoing express warranties of the Defendants. These warranties and representations were false in that FiberCel is unsafe and unfit for its intended uses.

62. As a result of the aforementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

**COUNT IV**
**INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS**

63. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if they were set forth at length herein, word for word.

64. Defendants' conduct as outlined above was intentional.

65. Defendants' conduct as outlined above was intended to cause or with reckless disregard for the probability of causing Plaintiff to suffer severe emotional distress, and was otherwise extreme, outrageous and of such character as not to be tolerated in a civilized society.

66. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and continues to suffer extreme mental distress, humiliation, anguish, emotional and physical injuries, and economic losses.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

a. Compensatory damages exclusive of interest and costs, in an amount to fully compensate Plaintiff for all past, present, and future pain and suffering.

b. Special damages, exclusive of interest and costs, in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;

c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the

safety and welfare of the general public and to the Plaintiff, in an amount sufficient to punish Defendants and deter future similar conduct;

d. An order to establish a medical monitoring protocol for Plaintiff to monitor her health;

e. Attorneys' fees, expenses, and costs of this action;

f. Pre-judgment and post-judgment interest in the maximum amount allowed by law;

g. Such other and further relief as this Court deems necessary, just, and proper; and

h. Judgment in her favor against Defendants, jointly and severally, in an amount that exceeds $75,000.00, exclusive of costs, interest and attorney fees, that is found to be consistent with the proofs set forth herein.

Respectfully submitted,

**THE SEGARS LAW FIRM**

/s/ Darryl K. Segars

By: _____

DARRYL K. SEGARS (P54997)
Attorneys for Plaintiff
615 Griswold St., Suite 913
Detroit, Michigan 48226
Phone: (313) 859-5500
Facsimile: (313) 859-5506
email: segarslaw@hotmail.com

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